

REMARKS

Applicants have carefully reviewed and considered the Office Action mailed on May 30, 2007, and the references cited therewith. Reconsideration and withdrawal of the rejections of the claims of the above-identified application in view of the amendments and remarks presented herein is respectfully requested.

Claims 1, 10, 11, 12, 14, and 22 are amended, claims 15-21 are canceled, and claims 23-26 were withdrawn; as a result, claims 1- 14 and 22 are now pending in this application.

Claims 23-26 are withdrawn because the Examiner made the Restriction Requirement final and examined only claims 1-14 and 22. Applicants retain the right to file any or all of the claims in other applications including continuation or divisional applications.

Support for the amendment to claim 1 is found in the specification at page 4, lines 1-4; page 6, line 7 through page 7, line 8; page 9, lines 1-7; and page 12, lines 22-29. Support for the amendment to claim 14 is found in the specification at page 9, lines 1-7. The amendments to claims 10-12 and 22 are made to further clarify Applicants' claims. Applicants believe that no new matter is added by the amendments to the claims and respectfully request their entry by the Examiner.

I. The Rejection under 35 U.S.C. §112

Claims 3-9 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. In the Office Action, the Examiner stated that the term “enriched,” as found in claims 3-9, is indefinite, as it is unclear what is encompassed by this term. This rejection is respectfully traversed.

A claim containing a form which is seemingly vague is not indefinite if it is clear when read in the context of the specification. In re Mattson, 184 U.S.P.Q. 484 (C.C.P.A. 1975); Andrew Corp. v. Gabriel Electronics, Inc., 6 U.S.P.Q. 2d 2010 (Fed. Cir. 1983). In the present specification, at page 6, lines 6-10, the term “enriched” is defined. For the convenience of the Examiner, that portion of the specification is provided hereinbelow:

As used herein, the term “enriched” refers to a composition or fraction wherein an object species has been partially purified such that, on a weight basis, the concentration of the object species is substantially higher than the naturally occurring level of the species in a finished product without fractionation.

Applicants' specification, at page 6, lines 6-10.

The definition of "enriched" is further illustrated in the specification at page 6, line 20 through page 7, line 8. In this section of the specification, examples are provided to illustrate what is meant by the term "enriched" within the context of the present invention. For example, at page 6, lines 21-23, the specification provides "the [salt whey protein] product comprises about 3 to 20 times the amount of lactoferrin that is typically present in whey or a whey protein product." Other examples are provided in the subsequent text. See specification at page 6, line 23 through page 7, line 8.

Reading claims 3-9 in view of the definition of "enriched" and the examples in the specification, it is clear that the protein product of claim 3 contains a concentration of lactoferrin that is substantially higher than the naturally occurring level of lactoferrin that is typically present in whey or a whey protein product. In other words, the protein product of claim 3 is increased in lactoferrin concentration. Similarly, it is also clear that the protein product of claims 4, 6, 7, 8, and 9 contains a concentration of lactoperoxidase, insulin-like growth factor 1 (IGF-1), transforming growth factor β 1 (TGF- β 1), transforming growth factor β 2 (TGF- β 2) and immunoglobulin G (IgG), respectively, that is substantially higher than the naturally occurring level of lactoperoxidase, insulin-like growth factor 1 (IGF-1), transforming growth factor β 1 (TGF- β 1), transforming growth factor β 2 (TGF- β 2) and immunoglobulin G (IgG), respectively, in whey or a whey protein product.

Additionally, it is clear that the growth factor of claim 5 contains a concentration of insulin-like growth factor 1 (IGF-1), transforming growth factor β 1 (TGF- β 1), or transforming growth factor β 2 (TGF- β 2), that is substantially higher than the naturally occurring level of insulin-like growth factor 1 (IGF-1), transforming growth factor β 1 (TGF- β 1), or transforming growth factor β 2 (TGF- β 2) in whey or a whey protein product. Thus, the term "enriched," as recited in Applicants' claims 3-9 is clearly defined and would be readily understood by one of ordinary skill in the art. The Examiner is respectfully requested to note that the claims need not be a technical dictionary, and are not required to define every term-of-art employed thereby.

As the term "enriched" is properly defined in Applicants' specification, withdrawal of the rejection of claims 3-9 under 35 U.S.C. § 112, second paragraph, is appropriate and is respectfully requested by Applicants.

II. The Rejection of the Claims under 35 U.S.C. §102(b) and 103(a)

Claims 1-14 and 22 were rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative under 35 U.S.C. § 103(a) as obvious over, Wu (U.S. Pub. No. 2002/0044998). This rejection is respectfully traversed.

Applicants' claims are directed to methods for preparing an enriched bioactive protein product from salt whey wherein fat is removed from salt whey to provide clarified salt whey, and salt is removed from the clarified salt whey to provide a protein product that is enriched for bioactive protein, as compared to the levels of bioactive protein in a corresponding protein product made from whey.

Applicants are also claiming a human nutritional product comprising a protein product manufactured according to the method of claim 1, wherein the product is selected from the group consisting of an infant formula, an adult nutritional product, a medical nutritional formula, a nutritional supplement product, and a nutritional food.

A. The Rejection under 35 U.S.C. §102

The Examiner's rationale for the rejection under §102(b) appears to be on the basis of anticipation by inherency. In the Office Action, the Examiner states that "[t]he claims appear to differ as to the recitation of specific bioactive proteins" and "[t]he bioactive proteins are inherent to that of Wu [U.S. Pub. No. 2002/0044998] as the same components and process steps are used." See Office Action, page 3, paragraphs 2 and 4. Applicants respectfully disagree with the Examiner's assertions.

Applicants respectfully assert that the Examiner has not established a *prima facie* case of anticipation or anticipation by inherency. Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration either explicitly or by inherency. *In re Dillon*, 919 F.2d 688, 16 USPQ 2d 1897, 1908 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991).

The Examiner is respectfully requested to note that inherency may not be established by probabilities or possibilities regarding what may have resulted in the prior art. *In re Oerlich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). M.P.E.P. 2112 states that an Examiner must

provide a rationale or evidence to support a rejection of inherency. Inherency, therefore, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” M.P.E.P. §2112. “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” M.P.E.P §2112 (emphasis in original). For the reasons provided hereinbelow, Applicants respectfully assert that the Examiner has not established a *prima facie* case of anticipation or anticipation by inherency.

The Wu publication discloses methods for making an α -lactalbumin enriched whey protein product by treating whey with an acid to lower the pH of the whey to 4.0 or lower, releasing calcium from the α -lactalbumin molecule, and precipitating the α -lactalbumin proteins in the acidified whey solution. Wu also discloses the α -lactalbumin enriched whey protein product produced by thus method.

The Examiner's assertion that the same components are used is erroneous. The starting material in the presently claimed process and product is salt whey, whereas the starting material used in the Wu publication is whey. One of ordinary skill in the art would recognize salt whey to be different than whey.

Evidence that one of ordinary skill in the art would recognize salt whey to be different than whey is found in Applicants' specification, in the Wu publication, and in the knowledge available to the art. In Applicants' specification at page 5, line 20 through page 6, line 4, "whey" and "salt whey" are defined. "Whey" is defined as the serum or watery part of milk that remains after coagulation of the solids, primarily in the production of cheese. Conversely, "salt whey" is a different solution. After "whey" is drained off the curd in the cheese-making process, the curd is then salted, and the solution that is collected following the salting of the curd is "salt whey." Additionally, at page 4, lines 1-4, Applicants' specification states that "salt whey is enriched for many bioactive proteins, such as lactoferrin, lactoperoxidase, immunoglobulin, and growth factors, e.g., TGF- β , and IGF-1, as compared to the levels of these bioactive proteins in whey." Thus, "whey" and "salt whey" are defined in the specification as different solutions that contain different concentrations of bioactive proteins.

Additionally, "whey" is defined in the Wu publication at page 2, col. A, para. 0019. The definition of whey in the Wu publication does not include "salt whey" or any definition of a liquid that an art worker would consider as salt whey.

As further evidence that one of ordinary skill in the art would readily understand "whey" and "salt whey" to be two different and distinct compositions, Applicants call the attention of the Examiner to two articles, a copy of each is enclosed herewith. See "Determination of the Volume of Industrial Waste from Wisconsin's Dairy Products Industry," K. Parmentier, May 9, 2000 (www.wastenot-organics.wisc.edu/library/whey.htm) and R. Kapoor and L.E. Metzger, J. Dairy Sci. 87: 1143-1150 (2004)("Evaluation of Salt Whey as an Ingredient in Processed Cheese"). Parmentier discusses the disposal of whey by landspreading, notes that salt whey is considered unusable and provides a table that clearly distinguishes whey and salt whey. (See Parmentier, at pages 1-2, and 3). Kapoor and Metzger state that "[s]alt whey, unlike sweet whey, cannot be conveniently processed because of its high salinity level." (See page 1143, column b). These articles evidence that the art worker recognizes "whey" and "salt whey" as two distinct and different by-products of the dairy industry.

Thus, the presently claimed process (claims 1-13), the product by process (claim 14) and the human nutritional product (claim 22) employ a different starting component than that disclosed in the process of the Wu publication.

The Examiner's assertion that the same process steps are used is also erroneous. The process steps provided in Applicants' claims, as presently amended, recite: a) removing fat from salt whey to provide clarified salt whey and b) removing salt from the clarified salt whey to provide a protein product that is enriched for bioactive protein, as compared to the levels of bioactive protein in a corresponding protein product made from whey. In contrast, the process steps disclosed in the Wu publication are lowering the pH of the whey protein product to 4.0 or below and fractionating the proteins in the acidified whey protein product to produce an α -lactalbumin enriched whey protein product. (See Wu publication, claim 1) The Wu publication does not disclose a method that recites the steps of removing fat from salt whey to provide clarified salt whey and removing salt from the clarified salt whey to provide a protein product that is enriched for bioactive protein, as compared to the levels of bioactive protein in a corresponding protein product made from whey. In fact, nothing in the Wu publication suggests

the purposeful removal of fat from whey, let alone from salt whey. Instead, Wu emphasizes the necessity of lowering the pH of the whey to 4.0 or lower. Thus, the presently claimed process (claims 1-13), the product by process (claim 14), and the human nutritional product (claim 22) employ different process steps than those disclosed in the Wu publication.

Finally, the resulting product of Applicants' process is a protein product that is enriched for bioactive protein, as compared to the levels of bioactive protein in a corresponding protein product made from whey. In sum, Applicants' starting material, process, and products are different than the material, process, and products disclosed in the Wu publication. Therefore, Applicants respectfully assert that the Examiner has not established a *prima facie* case of anticipation or anticipation by inherency, and that the instant application complies with 35 U.S.C. ' 102. Accordingly, withdrawal of the rejection under 35 U.S.C. ' 102 is proper and is respectfully requested.

B. The Rejection under 35 U.S.C. §103(a)

Applicants assert that the Examiner has not established a *prima facie* case of obviousness. The factual inquiries for the determination of obviousness, as set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), are as follows:

- 1) determine the scope and contents of the prior art;
- 2) ascertain the differences between the prior art and the claims at issue;
- 3) resolve the level of ordinary skill in the pertinent art; and
- 4) evaluate the evidence of secondary considerations.

Id. See also M.P.E.P. §2141; KSR v. Teleflex, U.S. Supreme Court, No. 04-1350 (April 30, 2007) (slip opinion). Applicants respectfully assert that the Examiner has not met the requirements for establishing a *prima facie* case of obviousness for the rejection of claims 1-14 and 22.

The entirety of the Wu publication teaches the art worker to prepare an α -lactalbumin enriched whey protein product from whey. There is no disclosure in the Wu publication of salt whey whatsoever. As discussed above, one of ordinary skill in the art of cheese production would appreciate the differences between salt whey and whey. Thus, it would not be logical for one of ordinary skill in the dairy and cheese making arts to attempt to prepare a protein product

from salt whey with the expectation that it would be enriched for bioactive protein, in view of art relating to a different process applied to whey.

Additionally, the Wu publication discloses a process that requires lowering the pH of the whey to 4.0 or lower. The Wu publication would lead the art worker to attempt to prepare a protein product by lowering the pH of whey to 4.0 or lower. The Wu publication simply does not teach or disclose preparing a protein product that is enriched for bioactive protein via the process steps of the present claims -- 1) the removal of fat from the salt whey to provide clarified salt whey, then 2) removing salt from the clarified salt whey to provide a protein product that is enriched for bioactive protein, as compared to the levels of bioactive protein in a corresponding protein product made from whey.

There is no logical reason for one of ordinary skill in the art who is interested in preparing an enriched bioactive protein product from salt whey would look to the Wu publication for guidance. In sum, the Wu publication does not render claims 1-14 and 22 obvious, and Applicants respectfully request that the rejection of the claims under 35 U.S.C. §103(a) be withdrawn.

RESERVATION OF RIGHTS

In the interest of clarity and brevity, Applicant may not have addressed every assertion made in the Office Action. Applicant's silence regarding any such assertion does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any cancelled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 349-9580 to facilitate prosecution of this application.


If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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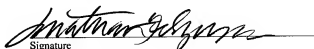
Date November 29, 2007

By


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